



Serial No.: 10/738,938  
Attorney Docket No.: 801204-0003

PFM

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Inventor(s)	:	Raul G. Barletta and Zhengyu Feng
Serial No.	:	10/738,938
Filing Date	:	December 17, 2003
Title	:	RECOMBINANT MYCOBACTERIA OVEREXPRESSING D-ALANINE LIGASE GENE AND USES THEREFORE
Group/Art Unit	:	1652
Examiner	:	Allyson Purnell
Confirmation No.	:	8745
Atty. Docket No.	:	801204-0003

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 C.F.R. § 1.56 and § 1.97(b), the references listed below and on the attached Form PTO/SB/08A (Substitute for Form 1449A-B/PTO) are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. Copies of the cited documents are enclosed. Submission of these references is not an admission that the references constitute prior art.

**U.S. PATENT DOCUMENTS**

Patent No.	Inventor(s)	Publication Date
2003/0133952	Raul G. Barletta and Ofelia Barletta-Chacon	July 17, 2003

**FOREIGN PATENTS**

Country	Patent No./Publication No.	Publication Date
None		

**Certificate of Mailing Under 37 C.F.R. 1.8**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on:

Date: October 14, 2004

Signature: Glen Gursley

Printed Name: Glen Gursley

The Director is hereby authorized to charge any additional amount required, or credit any overpayment, to Deposit Account No. 19-4409.

**OTHER REFERENCES**

BROWN, BARBARA A., et al., "Mycobacterium wolinskyi Sp. Nov. and *Mycobacterium goodii* Sp. Nov., Two New Rapidly Growing Species Related to *Mycobacterium smegmatis* and Associated with Human Would Infections: A Cooperative Study from the International Working Group on Mycobacterial Taxonomy", *International Journal of Systematic Bacteriology*. 1999, Vol. 49, p. 1493-1511.

HINGLEY-WILSON, SUZANNE M., et al., "Survival Perspectives from the World's Most Successful Pathogen, *Mycobacterium tuberculosis*", *Nature Immunology*. Oct. 2003, Vol. 4, No. 10, p. 949-955.

LAGIER, BEATRICE, et al., " Identification of Genetic Loci Implicated in the Survival of *Mycobacterium smegmatis* in Human Mononuclear Phagocytes", *Molecular Microbiology*. 1998, Vol. 29, No. 2, p. 465-475.

PIDDINGTON, DEBRA L., et al., "Cu,Zn Superoxide Dismutase of *Mycobacterium tuberculosis* Contributes to Survival in Activated Macrophages That Are Generating an Oxidative Burst", *Infection and Immunity*. Aug 2001, Vol. 69, No. 8, p. 4980-4987.

HARTH, GUNTER, et al., "High-Level Heterologous Expression and Secretion in Rapidly Growing Nonpathogenic Mycobacteria of Four Major *Mycobacterium tuberculosis* Extracellular Proteins Considered To Be Leading Vaccine Candidates and Drug Targets", *Infection and Immunity*, June 1997, Vol. 65, No. 6, p. 2321-2328.

MacGOWAN, ALASDAIR, et al., "In Vitro Models, In Vivo Models, and Pharmacokinetics: What Can We Learn from In Vitro Models?", *CID*. 2001 Vol. 33 (Suppl 3), p. S214-S220.

ORME, IAN M. and Collins, Frank M., "Mouse Model of Tuberculosis". Chapter 8, p. 113-134. *Tuberculosis: Pathogenesis, Protection and Control*, Barry R. Bloom (ed.), 1994, American Society for Microbiology, Washington, DC 20005.

McMURRAY, DAVID N., "Guinea Pig Model of Tuberculosis". Chapter 9, p. 135-147. *Tuberculosis: Pathogenesis, Protection and Control*, Barry R. Bloom (ed.), 1994, American Society for Microbiology, Washington, DC 20005.

DANNENBERG, JR., ARTHUR M., "Rabbit Model of Tuberculosis". Chapter 10, p. 149-156. *Tuberculosis: Pathogenesis, Protection and Control*, Barry R. Bloom (ed.), 1994, American Society for Microbiology, Washington, DC 20005.

THOEN, CHARLES O. "Tuberculosis in Wild and Domestic Mammals". Chapter 11, p. 157-162. *Tuberculosis: Pathogenesis, Protection and Control*, Barry R. Bloom (ed.), 1994, American Society for Microbiology, Washington, DC 20005.

JACOBS, JR., WILLIAM R. "Mycobacterium tuberculosis: A Once Genetically Intractable Organism", p. 1-16, *Molecular Genetics of Mycobacteria*, G.F. Hatful and W.R. Jacobs, Jr., (eds.), 2000, ASM Press, Washington, D.C.

BARLETTA, RAUL G. , et al. "Vaccines Against Intracellular Pathogens", *Subcellular Biochemistry*. 2000, Vol. 33, p. 559-599.

Applicants respectfully request that these references be made of record in the above-identified application and considered by the Examiner during prosecution of the application.

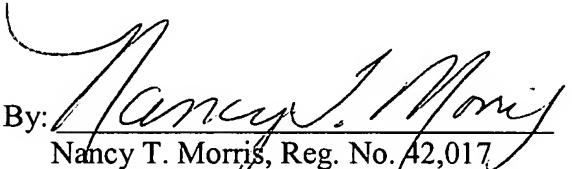
It is respectfully submitted that the present invention as claimed is patentable over the listed references.

This information disclosure statement is being filed before the mailing of a first Office Action on the merits. Accordingly, no fee is due.

Acknowledgment of receipt is respectfully requested.

Respectfully submitted,

By:

  
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Attorney for Applicant[s]



Substitute for Form 1449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number:	10/738,938
				Filing Date:	December 17, 2003
				First Named Inventor:	Raul G. Barletta
				Group Art Unit:	1652
				Examiner Name:	Allyson Purnell
Sheet	1	of	2	Attorney Docket Number:	801204-0003

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		2003/0133952		Raul G. Barletta and Ofelia Barletta-Chacon	July 17, 2003	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
			None					

**OTHER REFERENCES – NON PATENT LITERATURE DOCUMENTS AND INFORMATION**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		BROWN, BARBARA A., et al., "Mycobacterium wolinskyi Sp. Nov. and Mycobacterium goodii Sp. Nov., Two New Rapidly Growing Species Related to <i>Mycobacterium smegmatis</i> and Associated with Human Would Infections: A Cooperative Study from the International Working Group on Mycobacterial Taxonomy", <i>International Journal of Systematic Bacteriology</i> . 1999, Vol. 49, p. 1493-1511.	
		HINGLEY-WILSON, SUZANNE M., et al., "Survival Perspectives from the World's Most Successful Pathogen, <i>Mycobacterium tuberculosis</i> ", <i>Nature Immunology</i> . Oct. 2003, Vol. 4, No. 10, p. 949-955.	
		LAGIER, BEATRICE, et al., " Identification of Genetic Loci Implicated in the Survival of <i>Mycobacterium smegmatis</i> in Human Mononuclear Phagocytes", <i>Molecular Microbiology</i> . 1998, Vol. 29, No. 2, p. 465-475.	
		PIDDINGTON, DEBRA L., et al., "Cu,Zn Superoxide Dismutase of <i>Mycobacterium tuberculosis</i> Contributes to Survival in Activated Macrophages That Are Generating an Oxidative Burst", <i>Infection and Immunity</i> . Aug 2001, Vol. 69, No. 8, p. 4980-4987.	
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Examiner Signature		Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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Substitute for Form 1449B/PTO (Modified)			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)			Application Number:	10/738,938	
Sheet	2	of	Filing Date:	December 17, 2003	
			First Named Inventor:	Raúl G. Barletta	
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		JACOBS, JR., WILLIAM R. "Mycobacterium tuberculosis: A Once Genetically Intractable Organism", p. 1-16, <i>Molecular Genetics of Mycobacteria</i> , G.F. Hatful and W.R. Jacobs, Jr., (eds.), 2000, ASM Press, Washington, D.C.			
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Examiner Signature		Date Considered
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